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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,145	11/26/2001	Roland Green	700706.90076	8600

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,145

Applicant(s)

GREEN ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 3,6 and 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election traverse of Group I, Claims 1-6, filed 25 October 2002 in Paper No. 6 is acknowledged. In view of Applicant's comments and in view of the prior art, non-elected Claims 7-9 are rejoined with Claims 1-6.

Claims 1-9 are discussed below.

Claim Objections

2. Claims 3, 6 and 9 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 3, 6 and 9 are drawn to the "set of features" of Claims 1, 4 and 7 respectively wherein "the set of features contains a plurality of features". However, the "set of features" of Claims 1, 4 and 7 inherently contain more than one feature (i.e. a plurality). Therefore, Claims 3, 6 and 9 fail to further limit the subject matter of Claims 1, 4 and 7.

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Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-3 are indefinite in Claim 1 for the recitation "a set of features on a substrate, each of the features including single DNA probes" because it is unclear whether each feature of the set includes a single DNA probe (i.e. one probe); includes single-stranded DNA probes; includes multiple copies of a single DNA probe. It is suggested that Claim 1 be amended to clarify.

b. Claims 1-3 are indefinite in Claim 1 for the recitation "the probes for positive controls" because the recitation lacks proper antecedent basis in the claim. It is suggested that Claim 1 be amended to provide proper antecedent basis e.g. delete "the".

c. Claims 1-3 are indefinite in Claim 1 for the recitation "the probes for positive controls being arranged in a pattern recognizable to a human being" because it is unclear whether a physical relationship exists between the "pattern" and the "set of features".

d. Claims 2 and 3 are each indefinite for the recitation "the polynucleotide microarray of Claim 1" because the recitation lacks proper antecedent basis in the "DNA microarray" of Claim 1. It is suggested that Claims 2 and 3 be amended to provide proper antecedent basis e.g. replace "polynucleotide" with "DNA".

e. Claims 4-6 are indefinite in Claim 4 because the claim is drawn to a method for building a polynucleotide microarray. However, the method steps do not result in the building of a microarray. It is suggested that claim 4 be amended to resolve the claimed method e.g. at the end of the claim recite "wherein the arranged set of features provides a polynucleotide microarray."

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f. Claims 4-6 are indefinite in Claim 4 for the recitation "some of the features being positive controls" because the "features being" lacks proper antecedent basis in the claim, line 2 wherein each feature includes probes. It is suggested that Claim 4 be amended to provide proper antecedent basis e.g. replace "being" with "including".

g. Claims 4-6 are indefinite in Claim 4, lines 3, 4 and 5 for the recitation "positive controls" because it is unclear whether the positive controls are positive control probes. It is suggested that Claim 4 be amended to clarify e.g. replace "controls" with "control probes".

h. Claims 4-6 are indefinite in Claim 4, for the recitation "the positive control features" because the recitation lacks proper antecedent basis in line 3 which recites "features being (including) positive controls". It is suggested that Claim 4 be amended to provide proper antecedent basis e.g. replace "the positive control features" with "the features being (including) positive controls".

i. Claims 7-9 are indefinite in Claim 7 because the claim is drawn to a method for detecting whether an even of interest has occurred, but the method does not recite steps of detecting or detecting an event. It is suggested that Claim 7 be amended to recite method steps of detection as described in the specification.

j. Claims 7-9 are indefinite in Claim 7 for the recitation "the microarray including features intended to serve as positive controls" because it is unclear whether the features are positive controls. It is suggested Claim 7 be amended to clarify e.g. replace "intended to serve as" with "including".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lockhart et al (U.S. Patent No. 6,040,138, issued 21 March 2000).

Regarding Claim 1, Lockhart et al disclose a DNA microarray comprising a set of features on a substrate, each feature including single DNA probes (i.e. single-stranded probes) and probes for positive control arranged in a pattern recognizable to a human through visual observation i.e. normalization control probes located at the corners or edges of the array (Column 16, lines 1-31 and Column 24, lines 7-31).

Lockhart et al further disclose the array wherein whether an event of interest has occurred is determined by observation of the presence or absence of a visual pattern (Column 24, lines 7-31).

However, it is noted that the courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

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Regarding Claim 2, Lockhart et al disclose the microarray wherein the set of features contains one feature (Column 3, lines 7-29). The claim is drawn to a set of features which contains one feature. The term "contains" is open language. Therefore, the claimed "set of features which contains one feature" encompasses a set consisting of more than one feature. The microarray of Lockhart et al contains about 60 regions/cm² which contains one region i.e. feature as claimed (Column 2, lines 56-65).

Regarding Claim 3, Lockhart et al disclose the microarray wherein the set of features contains a plurality of features i.e. greater than about 60 regions (i.e. feature) /cm² (Column 2, lines 56-65).

Regarding Claim 4, Lockhart et al disclose a method for building a polynucleotide microarray comprising the steps of selecting a set of features, each feature including polynucleotide probes for detecting an event of interest wherein some of the features include control probes (Column 3, lines 7-39); and arranging the set of features on a microarray so that the positive controls form a pattern recognizable to a human being through visual observation if the positive control features fluoresce i.e. normalization control probes located at the corners or edges of the array (Column 16, lines 1-31 and Column 24, lines 7-31) wherein the pattern is recognizable via visual observation fluorescence from the positive controls (Column 16, lines 9-13).

Regarding Claim 5, Lockhart et al disclose the microarray wherein the set of features contains one feature (Column 3, lines 7-29). The claim is drawn to a set of features which contains one feature. The term "contains" is open language. Therefore, the claimed "set of features which contains one feature" encompasses a set consisting of more than one feature. The microarray of Lockhart et al contains about 60 regions/cm² which contains one region i.e. feature as claimed (Column 2, lines 56-65).

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Regarding Claim 6, Lockhart et al disclose the microarray wherein the set of features contains a plurality of features i.e. greater than about 60 regions (i.e. feature) /cm² (Column 2, lines 56-65).

Regarding Claim 7, Lockhart et al disclose a method for detecting whether an event of interest has occurred comprising: providing a DNA microarray comprising a set of features each including single-stranded DNA probes for detecting an event of interest and features intended to serve as positive controls which are arranged in a pattern recognizable to a human being through visual observation i.e. normalization control probes located at the corners or edges of the array (Column 16, lines 1-31); hybridizing nucleic acids from a sample to the microarray; and observing the presence or absence of the visual pattern (Example 1, Column 27, lines 14-Column 29, line 18).

Regarding Claim 8, Lockhart et al disclose the microarray wherein the set of features contains one feature (Column 3, lines 7-29). The claim is drawn to a set of features which contains one feature. The term "contains" is open language. Therefore, the claimed "set of features which contains one feature" encompasses a set consisting of more than one feature. The microarray of Lockhart et al contains about 60 regions/cm² which contains one region i.e. feature as claimed (Column 2, lines 56-65).

Regarding Claim 9, Lockhart et al disclose the microarray wherein the set of features contains a plurality of features i.e. greater than about 60 regions (i.e. feature) /cm² (Column 2, lines 56-65).

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7. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Noblett (U.S. Patent No. 6,362,004, filed 9 November 1999).

Regarding Claim 1, Noblett discloses a DNA microarray comprising a set of features on a substrate, each feature including single DNA probes (i.e. single-stranded probes) and probes for positive control arranged in a pattern recognizable to a human through visual observation i.e. fiducial control probes located at predetermined position and/or having a predetermined geometric shape (Column 5, lines 32-56 and Claims 1-6).

Noblett further discloses the array wherein whether an event of interest has occurred is determined by observation of the presence or absence of a visual pattern (Column 7, lines 31-54).

Regarding Claim 2, Noblett discloses the microarray wherein the set of features contains one feature (Column 5, lines 32-48 and Fig. 2 and 7). The claim is drawn to a set of features which contains one feature. The term "contains" is open language. Therefore, the claimed "set of features which contains one feature" encompasses a set consisting of more than one feature. The microarray of Noblett contains about a set of features which contains one feature (Fig. 2 and 7).

Regarding Claim 3, Noblett discloses the microarray wherein the set of features contains a plurality of features (Column 7, lines 9-21 and Fig. 6).

Regarding Claim 4, Noblett discloses a method for building a polynucleotide microarray comprising the steps of selecting a set of features, each feature including polynucleotide probes for detecting an event of interest wherein some of the features include control probes (Column 5, lines 32-56); and arranging the set of features on a microarray so that the positive controls form a pattern recognizable to a human being through visual observation if the positive control features fluoresce i.e. fiducial control probes located at predetermined position and/or having a predetermined geometric shape (Column 5, lines 32-56 and Claims 1-6).

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Regarding Claim 5, Noblett discloses the microarray wherein the set of features contains one feature (Column 5, lines 32-48 and Fig. 2 and 7). The claim is drawn to a set of features which contains one feature. The term "contains" is open language. Therefore, the claimed "set of features which contains one feature" encompasses a set consisting of more than one feature. The microarray of Noblett contains about a set of features which contains one feature (Fig. 2 and 7).

Regarding Claim 6, Noblett discloses the microarray wherein the set of features contains a plurality of features (Column 7, lines 9-21 and Fig. 6).

Regarding Claim 7, Noblett discloses a method for detecting whether an event of interest has occurred comprising: providing a DNA microarray comprising a set of features each including single-stranded DNA probes for detecting an event of interest and features intended to serve as positive controls which are arranged in a pattern recognizable to a human being through visual observation i.e. fiducial control probes located at predetermined position and/or having a predetermined geometric shape (Column 5, lines 32-56 and Claims 13-15); hybridizing nucleic acids from a sample to the microarray; and observing the presence or absence of the visual pattern (Column 7, lines 22-60).

Regarding Claim 8, Noblett discloses the microarray wherein the set of features contains one feature (Column 5, lines 32-48 and Fig. 2 and 7). The claim is drawn to a set of features which contains one feature. The term "contains" is open language. Therefore, the claimed "set of features which contains one feature" encompasses a set consisting of more than one feature. The microarray of Noblett contains about a set of features which contains one feature (Fig. 2 and 7).

Regarding Claim 9, Noblett discloses the microarray wherein the set of features contains a plurality of features (Column 7, lines 9-21 and Fig. 6).

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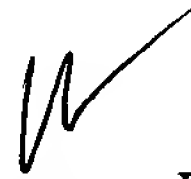
Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
January 6, 2003